

Remarks/Arguments:

Rejection under 35 U.S.C. § 103 -- Heyn in View of Marianne

Claims 1, 3-8, 10, 11, 17, 30, 32, 47 and 51 stand rejected under 35 U.S.C. § 103(a) as anticipated by U.S. Patent No. 5,201,757 to Heyn et al. (Heyn) in view of U.S. Patent No. 6,042,589 to Marianne (Marianne). Applicants respectfully submit that the pending claims, as amended are patentable over Heyn in view of Marianne for at least the reasons set forth below.

Independent claims 1 and 47 have been amended to more clearly define the respective inventions. Both claims now recite the structural relationship among the elements adapted to "reverse-deploy" the endoluminal device:

an anterograde sheath attached proximally to the distal tip, mounted over the endoluminal device in the anterograde portion of the introducer, and *axially moveable in a distal direction relative to the inner sheath by distally moving the shaft, wherein distal movement of the anterograde portion allows expansion of the endoluminal device from the compressed state to an expanded state starting with a proximal region of the device and progressing toward the device distal end;...* (Claim 1, emphasis added)

an anterograde portion, *axially movable in a distal direction relative to the retrograde portion . . . [and] an endoluminal device mounted concentrically over the shaft in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion, the distal portion constrained in a compressed configuration by the anterograde sheath and adapted to expand into an expanded state starting with a proximal region of the device and progressing toward the device distal end as the anterograde sheath is advanced distally;...* (Claim 47, emphasis added)

Furthermore, the independent claims have been amended to more clearly define the function of the anchoring means and the structure of the inflatable balloon, respectively:

...anchoring means in at least one of the retrograde portion or the anterograde portion for anchoring the endoluminal device proximal end in the expanded state in the body lumen to minimize relative axial movement between the proximal end of the device and the body lumen while a remaining portion of the endoluminal device distal of the proximal end is simultaneously unsheathed. (Claim 1)

...an inflatable balloon mounted radially inside the retrograde portion and sized to anchor the endoluminal device proximal end in the expanded state against the body lumen to minimize relative axial movement between the proximal end of the device and the body lumen while the endoluminal device distal portion is simultaneously unsheathed. (Claim 47)

The claimed features that permit fixation of the proximal end of a prosthesis in an expanded state while the remaining compressed distal portion is simultaneously unsheathed is advantageous in applications where accurate placement of the proximal end of the stent is desirable for successful treatment. See page 2, line 27 to page 4, line 6 of the specification as filed. The ability to control the proximal terminus of a prosthesis component is of particular use in branched lumen anatomies such as the intersection between the abdominal aorta and iliac arteries.

In contrast, neither of the devices of Heyn or Marianne are configured to anchor the *proximal* end of the prosthesis *in an expanded state* in the body lumen during a proximal-end-first delivery (i.e. reverse delivery), as claimed by the applicants. Heyn discloses a system in which the medial portion of a stent is deployed first, followed by the ends. Nowhere does Heyn disclose a structure for fixing the proximal end *in an expanded state against the body lumen* while the remainder of the stent is deployed. To the extent that Heyn discloses an inflatable balloon 140 in Fig. 9, that balloon does not anchor the proximal end in an expanded state against the body lumen, but rather is used for forcing opposing sleeves 120 and 122 to separate from one another, and at full inflation is not sized to hold the stent against the body lumen. Heyn, column 8, lines 11-60 and figures 7-9. Thus, the applicant's claims define a structure that is not taught or suggested by Heyn.

Accordingly, as applicants have asserted previously, neither the device disclosed by Heyn or Marianne is capable of placing the proximal end of the device in the body lumen before full deployment of the prosthesis, which is an advantage of the Applicants' claimed invention. Because Heyn opens from the middle, the device disclosed by Heyn can only be used to deploy the device from the middle to the ends, and offers no means for anchoring the proximal end of the device in an expanded state in the body lumen during deployment. Therefore, the user can only estimate where the proximal end will actually land. The device disclosed by Marianne is structured to retract the sheath from the distal end to the proximal end and is adapted to release the proximal end last. Thus, the user must place the proximal end of the device by first partially deploying the distal end of the device, anchoring the proximal end against sheath 16, and then moving the partially deployed device to the desired position before releasing the proximal end. See Marianne, column 3, lines 5-41. By contrast, Applicants claimed invention allows the user to *deploy and anchor* the proximal end first *in an expanded state* in the precise location desired while the remainder of the stent is still compressed, and then deploy the rest of the stent from the proximal to the distal end.

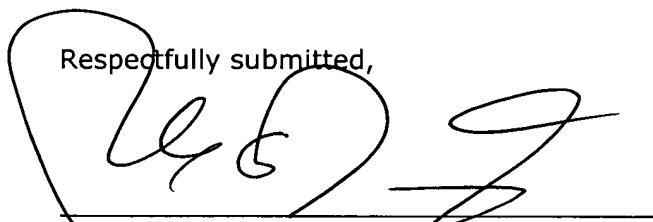
Because both claims 1 and 47 include elements that are neither disclosed nor suggested by Heyn or Marianne, alone or in combination, these claims should be allowed, and claims 3-8, 10, 11, 17, 30, 32, and 51, which are dependent upon claim 1, should also be allowed at least as being dependent upon an allowable base claim.

The applicants have considered the Advisory Action issued in reply to the applicant's response to the Final Office Action and the characterization in that Action that the language relating to deployment from the proximal to the distal end as pending in the claims at that time, recited an "intended use." Although the applicants disagree with that characterization, the applicants respectfully submit that the claims, as amended, now clearly define structural relationships among elements that must be considered when examining the application, and that clearly distinguish from the cited references.

Conclusion:

In view of the points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested. As a number of withdrawn claims are also dependent from allowable claims, the applicants further request allowance of such withdrawn claims as well. Should the Examiner still believe that any of the claims are not allowable for any reason, Applicants respectfully request a telephone interview to further discuss the merits of this application.

Respectfully submitted,


Rex A. Donnelly, Reg. No. 41,712
Phillip E. Gonzalez, Reg. No. 55,213
Attorneys for Applicants

RAD/peg

Dated: February 9, 2005

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

Appn. No.: 10/081,641
Amendment Dated February 9, 2005
Reply to Office Action of November 9, 2004



BSI-486US

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. 18-0350 of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

February 9, 2005

Rick Duran

RAD_I:\BSI\486US\RESPONSE 11-09-2004.DOC